

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY  
TRENTON DIVISION**

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| <b>ASTRAZENECA AB, et al.,</b>     | ) Docket No. 3:15-cv-03375-FLW-DEA |
|                                    | )                                  |
| <b>Plaintiffs,</b>                 | ) Courtroom No. 6W                 |
|                                    | ) Clarkson S. Fisher Building      |
| <b>versus</b>                      | ) & U.S. Courthouse                |
|                                    | ) 402 East State Street            |
| <b>TORRENT PHARMA INC. et al.,</b> | ) Trenton, New Jersey 08608        |
|                                    | )                                  |
| <b>Defendants.</b>                 | ) July 6, 2016                     |
|                                    | ) 10:53 a.m.                       |

**TRANSCRIPT OF TELEPHONIC STATUS CONFERENCE  
BEFORE HONORABLE DOUGLAS E. ARPERT  
UNITED STATES MAGISTRATE JUDGE**

|                     |                              |
|---------------------|------------------------------|
| For the Plaintiffs: | McCarter & English LLP       |
|                     | By: JOHN E. FLAHERTY, ESQ.   |
|                     | AYA CIESLAK-TOCHIGI, ESQ.    |
|                     | Four Gateway Center          |
|                     | 100 Mulberry Street          |
|                     | Newark, New Jersey 07102     |
|                     | <br>Covington Burling, LLP   |
|                     | By: MICHAEL N. KENNEDY, ESQ. |
|                     | One City Center              |
|                     | 850 Tenth Street, NW         |
|                     | Washington, DC 20001-4956    |

|                       |                     |
|-----------------------|---------------------|
| ESR/Courtroom Deputy: | Charmaine Ellington |
|-----------------------|---------------------|

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APPEARANCES:  
(Continued)

|   |   |
|---|---|
| For the Defendants:                       | NANCY ZHANG, ESQ.<br><br>HaynesBoone<br>By: JOHN W. BATEMAN, ESQ.<br>800 17th Street, NW<br>Suite 500<br>Washington, DC 20006<br><br>Wiley Rein LLP<br>By: RACHEL HUNNICUTT, ESQ.<br>1776 K Street NW<br>Washington, DC 20006   |
| For Hetero USA, Inc.:                     | Hill Wallack, LLP<br>By: CHRISTINA L. SAVERIANO, ESQ.<br>21 Roszel Road<br>Princeton, New Jersey 08543  |
| For Citron Pharma<br>LLC:                 | Rivkin Radler LLP<br>By: NANCY ANN DEL PIZZO, ESQ.<br>21 Main Street, Suite 158<br>Court Plaza South, West Wing<br>Hackensack, New Jersey 07601<br><br>Axinn Veltrop & Varkrider LLP<br>By: JOSH REISBERG, ESQ.<br>114 W. 47TH Street, 22nd Floor<br>New York, New York 10036 |
| For Torrent:                              | Brown Moskowitz & Kallen, PC<br>By: REBEKAH R. CONROY, ESQ.<br>180 River Road<br>Summit, New Jersey 07901<br><br>Robins Kaplan LLP<br>By: JEFFREY HOVDEN, ESQ.<br>601 Lexington Avenue<br>Suite 3400<br>New York, NY 10022  |
| For Breckenridge<br>Pharmaceutical, Inc.: | Fleming Ruvoldt PLLC<br>By: ROBERT JOSEPH FETTWEIS, ESQ.<br>250 Moonachie Road<br>Suite 501<br>Moonachie, New Jersey 07074  |

APPEARANCES:  
(Continued)

For Mylan  
Pharmaceuticals Inc.:

Saiber LLC  
By: ARNOLD B. CALMANN, ESQ.  
One Gateway Center, 10th Floor  
Newark, New Jersey 07102-5311

Wilson Sonsini Goodrich & Rosati  
By: TUNG-ON KONG, ESQ.  
One Market Plaza  
Spear Tower, Suite 3300  
San Francisco, California 94105

For Micro Labs  
USA and Apotex:

Carella Byrne Cecchi Olstein  
Brody & Agnello, PC  
By: MELISSA E. FLAX, ESQ.  
5 Becker Farm Road  
Roseland, New Jersey 07068

Taft Stettinius & Hollister LLP  
By: ANDREW N. ALUL, ESQ.  
BRIAN P. MURRAY, ESQ.  
111 East Wacker  
Suite 2800  
Chicago, Illinois 60601

For Princeton  
Pharmaceutical, Inc.:

Fox Rothschild, LLP, PC  
By: KAREN A. CONFOY, ESQ.  
997 Lenox Drive, Building 3  
Lawrenceville, New Jersey 08648

For Zydus  
Pharmaceuticals (USA),  
Inc.:

Locke Lord LLP  
By: ELISSA J. GLASBAND, ESQ.  
44 Whippany Road  
Morristown, New Jersey 07960

For Strides Pharma,  
Inc.

Budd Larner, PC  
By: MICHAEL H. IMBACUAN, ESQ.  
150 John F. Kennedy Parkway  
CN 1000  
Short Hills, New Jersey 07079

1           TRENTON, NEW JERSEY   JULY 6, 2016,   10:53 A.M.

2           THE COURT:   This is the consolidated Roflumilast  
3 cases.   It's consolidated with Judge Wolfson under Civil Action  
4 Number 15-3375.   I apologize for the confusion.

5           Counsel, I have all of your appearances noted, and  
6 I'm not going to take the time to have you restate them on the  
7 record.   But I would appreciate if you'd identify yourselves as  
8 you speak.

9           My thought, in terms of an agenda for this morning,  
10 was to start with plaintiffs' counsel and see what the current  
11 status is, what open items we have that need to be addressed,  
12 and then ask defense counsel to add any additional items of  
13 interest or concern to the agenda, and then work our way  
14 through them.

15           So, Mr. Flaherty, good morning.   I'll start with you  
16 on behalf of plaintiffs to see an overview of where you see the  
17 case -- cases, and the items that you think need to be  
18 addressed today, please.

19           MR. FLAHERTY:   Good morning, Your Honor.   Michael  
20 Kennedy from Covington Burling is on the line, and he'll be  
21 able to discuss those issues today.

22           THE COURT:   Thank you.   Good morning, Mr. Kennedy.

23           MR. KENNEDY:   Good morning, Your Honor.   This is Mike  
24 Kennedy with Covington on behalf of the plaintiffs.

25           We only have one issue for today, aside from which we

1 have a claim construction hearing next week, and from  
2 plaintiffs' perspective, fact discovery in proceeding.

3           Plaintiffs do have a pending motion to compel that we  
4 -- against four of the defendants that we filed a letter June  
5 27th. And three of the four defendants filed an opposition  
6 letter on July 1st. And this has to do with the motion to  
7 compel production of certain active ingredient samples for the  
8 defendants in question that have expired.

9           THE COURT: Right. I'm --

10           MR. KENNEDY: And plaintiffs have moved to compel  
11 production. I'm happy to address that motion, if Your Honor  
12 would like.

13           THE COURT: Let's come back to it in one minute. I  
14 have Mr. Flaherty's letter of June 27th, which appears on the  
15 docket as Entry Number 96. And I also have Ms. Flax's letter  
16 of July 1, which appears as Entry Number 99 on the docket. And  
17 I am prepared to discuss the issues raised in that  
18 correspondence with you this morning.

19           So in sum then, the report from the plaintiffs is  
20 that things are progressing according to schedule, including a  
21 claim construction hearing set for next week with Judge  
22 Wolfson, and you'd like me to address the informal motion that  
23 we just discussed.

24           Is there anything else you think out to be on the  
25 agenda for the call today, Mr. Kennedy?

1 MR. KENNEDY: No, Your Honor.

2 THE COURT: Okay; thank you.

3 From the -- from the defense perspective, is there  
4 anything in addition to what Mr. Kennedy has laid out that  
5 anyone thinks needs to be addressed on this call today?

6 (No audible response heard)

7 THE COURT: Okay.

8 MR. HOVDEN: No, Your Honor, not from --

9 THE COURT: Who was speaking, please?

10 MR. HOVDEN: Jeff Hovden for Torrent. And Torrent  
11 has no other issues.

12 THE COURT: Okay; thank you.

13 Let me ask this question: In reviewing the docket in  
14 anticipation of the call, I see a letter dated May 19,  
15 submitted by Mr. Calmann as an unopposed application for leave  
16 to amend Mylan's non-infringement and invalidity contentions,  
17 and a proposed order attached.

18 Mr. Calmann, do you know whether that order was  
19 entered?

20 (No audible response heard)

21 THE COURT: Perhaps we've lost Mr. Calmann.

22 MR. KONG: Your Honor, this is T.O. Kong for Mylan --  
23 national counsel for Mylan, if I may address that. I do not  
24 believe the Court has taken action on that motion. And I think  
25 that (indiscernible 10:58:10) submitted a similar letter, that

1 letter also is pending before the Court.

2 THE COURT: Okay. I appreciate that, and I assume  
3 there is no objection then to my entering that order submitted  
4 by Mylan today, correct?

5 UNIDENTIFIED ATTORNEY: No objection --

6 UNIDENTIFIED ATTORNEY: That's correct, Your Honor.

7 THE COURT: Okay.

8 MR. ALUL: Your Honor, this is Andy Alul for  
9 defendants Apotex and Micro Labs.

10 We also have a similar letter on file that is an  
11 unopposed motion for leave to serve supplemental invalidity  
12 contentions, as well. And we would hope -- we would request  
13 that the Court consider that letter and proposed order, as  
14 well.

15 THE COURT: I have that in front of me, as well;  
16 thank you. That came in -- together with correspondence from  
17 Ms. Flax dated June 9. And I will take care of entering that  
18 order after the call today, as well. Okay.

19 Before I -- we move on --

20 MR. CALMANN: Your Honor, this is --

21 THE COURT: Go ahead.

22 MR. CALMANN: Your Honor?

23 THE COURT: Yes?

24 MR. CALMANN: Your Honor, this is Arnie Calmann. I'm  
25 sorry to interrupt, I just wanted to apologize. I heard you

1 mention my name just as I got disconnected, there's a lot of  
2 electrical (indiscernible 10:59:25) me at the moment. I  
3 apologize.

4 THE COURT: No -- no trouble. Your colleague  
5 responded to my question, and we've resolved the -- we resolved  
6 the issue. It was about an unsigned order that you submitted  
7 back in May, and just a little bit of housekeeping. So we've  
8 taken care of it; thank you.

9 MR. CALMANN: Thank you, Your Honor.

10 THE COURT: All right. Are there any other -- before  
11 we move on to the substantive issue of plaintiffs' application,  
12 are there any other housekeeping items that should be  
13 addressed? Are there any -- any other party that has an open  
14 order or request to the Court that has not been addressed to  
15 date?

16 (No audible response heard)

17 THE COURT: Okay. Are we currently operating under a  
18 current case management order? In other words, are the dates  
19 that you all are operating under from a prior order operative?  
20 Are they still governing what's going on? In other words, do  
21 we -- is our scheduling order adequate as we sit here?

22 MR. KENNEDY: Your Honor, this is Mike Kennedy from  
23 Covington.

24 From plaintiffs' perspective, the scheduling order is  
25 Docket Entry 37, appears to be operative except we cut the



1 claim construction hearing down to one day on the 12th, that's  
2 actually been taken care of.

3 THE COURT: Does anybody think differently? In other  
4 words, everybody is content with the current case management  
5 order as it stands?

6 (No audible response heard)

7 THE COURT: Okay; thank you for that. All right.

8 So what I'm left with, it seems, is an informal  
9 application brought on behalf of the plaintiffs. It's a  
10 dispute concerning a refusal by some defendants to produce  
11 samples of -- at least it's characterized by plaintiff, a  
12 refusal by some defendants to produce samples of the active  
13 ingredient in their respective ANDA products. The defendants -  
14 -, Apotex, Mylan, Princeton, and Torrent -- apparently have  
15 withheld production of these samples on the grounds or on the  
16 basis that the samples have expired. And that issue is the  
17 subject of the two submissions that I received.

18 The defendants argue that they have produced samples  
19 in their final formulate -- of their final formulated products,  
20 and because the samples that the plaintiffs seek are expired  
21 and will not be used to formulate the defendants' ANDA  
22 products, that they are not representative of the products that  
23 the defendants will produce and market, and as a result, there  
24 is no relevance to those samples.

25 Have I -- Mr. Kennedy, have I captured the essence of

1 the dispute? Anything you want to add?

2 MR. KENNEDY: Your Honor, there are a few things I'd  
3 like to add, but I think that is the essence of what I  
4 understand to be plaintiffs' position.

5 THE COURT: Okay. Go ahead.

6 MR. KENNEDY: I'm sorry; defendants' position.

7 THE COURT: Yeah, go ahead, I'll -- I'll hear you.

8 MR. KENNEDY: The point I'd -- the point I'd make  
9 here is that defendants -- first of all, they've never -- the  
10 defendants opposing the motion have never contended that  
11 producing the expired API would be an undue burden. And they  
12 also don't have unexpired API samples. All they have from the  
13 API perspective is expired. And their argument for relevance  
14 is based on essentially a scientific dispute that is going to  
15 be hotly disputed between the parties when we get to expert  
16 discovery. And I don't think it would be appropriate for the  
17 Court at this point to essentially make a ruling on that  
18 scientific issue by saying that the expired samples are  
19 irrelevant.

20 THE COURT: Well, let's talk about --

21 MR. KENNEDY: I think (indiscernible - multiple  
22 speakers 11:04:02).

23 THE COURT: Let's talk -- excuse me. Let's talk  
24 about their relevance for a minute. They -- is it -- is it, in  
25 fact, true that the resisting defendants here have each

1 produced samples of their final formulated products?

2 MR. KENNEDY: They've agreed to; I'm not sure they've  
3 all produced them yet. I think they're in -- some are in the  
4 process of. But, yes, we expect to get finished samples from  
5 everybody.

6 THE COURT: Okay. So if those are the products that  
7 will ultimately be the subject of the dispute, what is the  
8 relevance of the expired products? I know there is a  
9 scientific argument about the degradation of the product, and I  
10 may not -- I may not have the right terminology here, but I  
11 think -- I think everybody agrees that over time, this product  
12 -- this product does degrade.

13 So why are we -- why are we focused on products that  
14 we know are expired? And why aren't we focused on the products  
15 that are in the final formulated form?

16 MR. KENNEDY: Well, let me answer that in two parts,  
17 Your Honor:

18 First of all, plaintiffs don't agree that 4-Hydroxy  
19 Impurity is a degradation product. And I'm happy to address  
20 the document that the defendants attach to their motion, but  
21 that -- but that's the hotly disputed issue I was referring to.

22 Defendants, as I understand it, contend that the 4-  
23 Hydroxy Impurity within the claim is a degradation product of  
24 Roflumilast. Plaintiffs disagree with that, at least under  
25 those conditions.

1           And, in fact, the data in Exhibit A to their  
2 opposition shows that several of the tests -- the stability  
3 tests that are set forth in that 2009 document don't show any  
4 formulation of the 4-Hydroxy Impurity. The only test that  
5 appeared to show that after six months was under Artificial  
6 Accelerated (indiscernible 11:06:20).

7           So I think this gets back to my point that defendants  
8 are asking Your Honor to make a ruling on a disputed issue that  
9 really is going to be addressed by experts in the trial. And  
10 they've provided no context through the document for their --  
11 for their argument on the degradation argument. They've done  
12 nothing to connect up this 2009 Takeda document to their own  
13 products.

14           So I just wanted to clarify that there is no  
15 agreement about whether this was actually a degradation  
16 product.

17           As for the relevance, you know, we'll have expert --  
18 expert discovery isn't for several months. Plaintiffs are  
19 considering running any number of tests to confirm that  
20 defendants infringe these three patents that require the  
21 presence of the small amount of 4-Hydroxy Impurity, and we --  
22 the API samples are not cumulative necessarily for the finished  
23 dosage form samples. You know, there are different tests that  
24 one could run on just an API versus the finished dosage form.  
25 And that, you know, again, that's really for experts to sort

1 out.

2 But the case law -- including the case law defendants  
3 cite -- makes clear that in making the ultimate determination  
4 of infringement based on the product (indiscernible 11:07:45),  
5 courts can consider a wide variety of evidence, including  
6 samples, including test data, extrinsic to the ANDA itself.  
7 You know, one example that states you look at all the relevant  
8 evidence is the Glaxo case from 1997, but --

9 THE COURT: Well --

10 MR. KENNEDY: -- but really all the cases defendants  
11 cite stand for our proposition.

12 THE COURT: Well, let's talk about that Glaxo case  
13 for a minute. Because one -- one -- at least one, and perhaps  
14 a primary consideration is what is likely to be sold, or  
15 preferably what will be sold, will ultimately determine whether  
16 infringement exists. And if you look at the five bullet points  
17 in Ms. Flax's letter that she -- on Page 3 that she titles  
18 "Undisputed Facts Material to Relevancy," she lays out five  
19 facts that she contends are undisputed:

20 Defendants will be manufacturing their ANDA products  
21 overseas. Will only be importing into the United States for  
22 sale the formulated tablets;

23 Number two, defendants will not be importing into the  
24 United States the unformulated API, and will have no  
25 involvement with such, expired or otherwise;

1           Number three, defendants will only be using unexpired  
2 Roflumilast API to prepare their products;

3           Number four, defendants will not be using the expired  
4 API to formulate;

5           And, number five, defendants will not be marketing or  
6 selling formulated products with the expired API.

7           I mean if all of those facts are so, and the test is  
8 what is likely to be sold or what will be sold, I'm still  
9 struggling to understand the need for this substance, this  
10 expired product.

11           MR. KENNEDY: Your Honor, none of those five bullet  
12 points preclude plaintiffs from making the following findings -  
13 - or following showing:

14           That -- let's say we test the expired API using an  
15 expert. And the expert testifies the 4-Hydroxy Impurity is  
16 there.

17           And the expert further shows and testifies at trial  
18 that if the 4-Hydroxy in the expired sample also would have  
19 been in the same sample when it was unexpired, therefore, the  
20 sample provided by the defendants is representative of what  
21 defendant would sell upon approval and, therefore, defendants'  
22 product, if sold, would infringe.

23           There is expert testimony that would to connect up a  
24 couple of those points, but, you know, that's something that's  
25 done in numerous ANDA cases. And, you know, defendants' view

1 of the world is very (indiscernible 11:10:45) and not  
2 consistent with the case law, and not representative of how  
3 these infringement cases are made.

4 And, again, I also get back to the point that there  
5 is expert testimony that will flush out some of these points  
6 and connect-up the expired API to the product that would be  
7 sold upon approval.

8 THE COURT: Help me with that last statement. Can  
9 you give some proffer of how you're going to connect-up how the  
10 expired product gets linked up to the product that's ultimately  
11 sold? They're --

12 MR. KENNEDY: Sure, Your Honor.

13 THE COURT: The defendants --just put a finer point  
14 on it, the defendants have made a series of representations  
15 that no such connection will occur, or can occur, or --

16 MR. KENNEDY: Sure, Your Honor. So let's say we test  
17 the expired API and we find the 4-Hydroxy Impurity, we would  
18 expect to have expert testimony to show that because the 4-  
19 Hydroxy Impurity is not a degradation product, the 4-Hydroxy  
20 Impurity in the expired sample would also have been present in  
21 the unexpired sample. In other words, when the sample had  
22 been unexpired.

23 And remember, these defendants say they don't have  
24 any unexpired samples to test. And, therefore, because the  
25 presently expired sample is not a degradation product, so it

1 would have been present in unexpired samples and, therefore, it  
2 is evidence of infringement for the fact finder to weigh.

3 THE COURT: Okay.

4 MR. KENNEDY: And we would expect to be able to make  
5 that showing at trial.

6 THE COURT: Okay; thank you.

7 MR. KENNEDY: But since they don't have unexpired  
8 API, we would need the expired API to have an opportunity to  
9 make that showing.

10 THE COURT: All right. I interrupted you. Is there  
11 anything else you wanted to say, Mr. Kennedy?

12 MR. KENNEDY: Just very quickly. You know, I think  
13 the prematurity of this motion is shown by how defendants argue  
14 it. They use terms such as "producing the expired API would  
15 cause a prejudice, and it would confuse the case." Those are  
16 arguments that are typically made, as Your Honor knows, in the  
17 context of like a Federal Rules of Evidence 403 motion. And,  
18 in fact, Your Honor, their cases they cite in their opposition,  
19 the SmithKline case was actually in that posture. And, you  
20 know, one of the reasons that motion in limine was granted as  
21 to unexpired -- or as to expired samples is because it appeared  
22 there were unexpired samples available in that case. And that  
23 was also after they were done expert discovery to flush out the  
24 issue.

25 Defendants are trying to make the same type of 403



1 argument, something like six months before opening expert  
2 reports, and in the context of discovery that they have never  
3 contended would represent an undue burden to provide. And  
4 under Rule 26, I think the balance fits very strongly in favor  
5 of ordering defendants to produce these samples. I'd like to  
6 make these kinds of arguments after we've had expert discovery,  
7 and after the issue's been flushed out.

8           So unless Your Honor has any other questions, you  
9 know, that's our position.

10           THE COURT: All right. Thank you. Ms. Flax, you or  
11 someone on the -- on behalf of the defendants who are resisting  
12 production of this material want to -- want to add anything to  
13 the July 1st submission?

14           MR. ALUL: Good morning, Your Honor. This is Andy  
15 Alul for defendants Apotex and Micro Labs.

16           At the outset, I would like to note that plaintiffs  
17 have failed in their meet and confer obligations for the simple  
18 fact that none of these alleged grounds for relevancy were  
19 brought during the meet and confer process.

20           What Mr. Kennedy has just proposed to the Court  
21 regarding relevancy is news to us, at least to me. It was  
22 something I never heard during the meet and confer process. It  
23 was something that was never set forth in their letter to the  
24 Court -- their letter motion to the Court. You would have  
25 thought -- or one would have thought that to the extent that

1 they really believed in this relevancy argument, they would  
2 have supported this argument with maybe a declaration from  
3 their expert. But they never did.

4           So I'm at a little bit of a disadvantage here because  
5 this is the first time I've heard this alleged relevancy  
6 argument where they kept expired API and have an expert come in  
7 and say, "Well, we found the 4-Hydroxy Impurity in the expired  
8 API and we think, therefore, it should be present in the  
9 unexpired version of that API, and that that would have been  
10 used to formulate the ANDA product." This is something we  
11 haven't heard before yet.

12           So I'm at a little bit of a disadvantage here, but  
13 I'll try my best to explain our position as to why we believe  
14 the expired API is relevant. As Your Honor noted, we had at  
15 the top of Ms. Flax's letter at Page 3, five undisputed facts  
16 that we think support denial of plaintiffs' application. And  
17 the first one is, Your Honor, that -- the first two are  
18 basically that we are foreign manufacturers. We are only going  
19 to be importing to the United States finished dosage form,  
20 i.e., our formulated tablets.

21           Our pre-formulated API is never going to step foot in  
22 the United States. So it cannot be the subject of an  
23 infringement charge from plaintiffs in this case.

24           What they're trying to do is weave a circumstantial  
25 evidence case. They're saying, well, you know, we found the 4-

1 Hydroxy Impurity in your pre-formulated API and, therefore,  
2 you're going to formulate your ANDA product and so it should  
3 have it in there when it comes into the United States.

4 That's all stuff that's just very remote and  
5 speculative, and I'm not sure that it could be the basis for  
6 their relevancy argument.

7 But even more importantly, Your Honor, as the Court  
8 noted, you know, to the extent that any of the defendants have  
9 had -- have unexpired API samples, they've produced them. A  
10 few of the defendants, including my clients -- one of my  
11 clients does not have any unexpired APIs left because they  
12 (indiscernible 11:17:09) their APIs to a non-party to this case  
13 that plaintiffs haven't sued.

14 So we've produced finished dosage form tablets,  
15 that's what plaintiffs need to focus on for infringement in  
16 this case.

17 And their -- their argument for relevancy is just  
18 speculative, and based on unsupported attorney arguments, and I  
19 just don't really know what to make of it other than that.

20 So we maintain our position that the expired samples  
21 are irrelevant, Your Honor. And I think as the Court noted,  
22 the five undisputed facts that we brought to the Court's  
23 attention really support denial of plaintiffs' application, and  
24 I'd be happy to answer any further questions the Court has.

25 THE COURT: All right. Thank you. Let me start with

1 your first point: Would a further meet and confer, now that  
2 you've heard a more expansive argument from the plaintiffs  
3 regarding relevance, do you think a further meet and confer is  
4 going to have any beneficial effect on the defendants' position  
5 regarding production?

6 MR. ALUL: Your Honor, I'm always open to something  
7 like that. But I think -- as I think through this, I just -- I  
8 continue to believe that their argument for relevancy is  
9 speculative.

10 THE COURT: I --

11 MR. ALUL: And regarding --

12 THE COURT: My question --

13 MR. ALUL: (Indiscernible - multiple speakers  
14 11:18:44) if I may --

15 THE COURT: One second. My question was somewhat --  
16 was somewhat disingenuous in that my sense is that given the  
17 overall position the defendants have taken on relevance, that  
18 further time spent in a meet and confer context is not likely  
19 to be -- is not likely to be productive, right? If I'm --

20 MR. ALUL: I would agree.

21 THE COURT: Okay. So let me propose this idea, and  
22 see what you all think of it. I guess my thinking could best  
23 be described as skeptical with respect to the relevance of this  
24 request, but I'll suggest maybe a better term is "uneducated,"  
25 at least for the time being.

1 I understand the arguments being proffered, but I'm  
2 having a hard time, to be candid, Mr. Kennedy, in connecting  
3 the dots that you and the plaintiffs would have me connect on a  
4 relevance argument between this unexpired -- I'm sorry --  
5 expired product and ultimately your arguments on infringement.

6 And I think perhaps the Court would benefit from a  
7 declaration or submission from one of plaintiffs' experts  
8 filling out the argument on what it is you say could have  
9 bearing on the issues in this case, and what the experts  
10 propose to do in that regard.

11 And then once that declaration has been produced,  
12 maybe that's the time for you and defense counsel to circle  
13 back in a brief meet and confer to see whether there's anything  
14 disclosed via that declaration that gives the defendants a  
15 basis to reconsider, and an opportunity to respond to it, if  
16 they choose. And then I think I would be more comfortable  
17 making a decision on this -- on this subject.

18 So I put that out there, not as the final word, but  
19 as a -- as a suggestion for your consideration. Mr. Kennedy?

20 MR. KENNEDY: Your Honor, I'm thinking it through in  
21 my mind that maybe a productive way to proceed -- I guess my --  
22 candidly my initial reaction is that I fear that it could set  
23 up kind of a satellite litigation over an issue that would be  
24 dealt with in the ordinary course through expert discovery.  
25 But I -- you know, it's certainly something, you know, I'm

1 happy to consider and -- and, you know, we could probably do  
2 it.

3           You know, the only other thing I'd say is that I  
4 think the defendants -- their July 1st letter had, you know,  
5 assertions that probably could benefit from, you know, an  
6 expert declaration, as well. You know, and Mr. Alul's point,  
7 you know, I think -- you know, in responding to a letter orally  
8 that we didn't have in writing, I think that's, you know, where  
9 a lot of these expert issues get flushed out.

10           But would Your Honor contemplate some kind of  
11 exchange of declarations or plaintiffs go first, and defendants  
12 respond? I just want to understand the idea.

13           THE COURT: Well, I'm -- I'm to suggestions in terms  
14 of staging and, you know, the -- whatever this process is. I  
15 mean I -- ultimately I'm confessing to the -- to the group here  
16 that I'm having trouble getting my head around the relevance  
17 argument, and I'm trying to give plaintiffs an opportunity to  
18 give me some help here. And, of course, I want to give  
19 defendants an opportunity to respond to whatever help you  
20 offer.

21           So whether we do it simultaneously, whether you all  
22 exchange them among yourselves and submit them simultaneously,  
23 I'm open to whatever process works for everybody. But on the  
24 basis of what I have in front of me right now, I'm -- I'm  
25 struggling.

1 MR. ALUL: Your Honor, this --

2 MR. KENNEDY: Your Honor, let me --

3 MR. ALUL: This is -- I'm sorry. This is Andy Alul  
4 on behalf of Apotex.

5 We're certainly agreeable to the procedure the Court  
6 proposed, and we think it's probably a good idea. Because,  
7 again, plaintiffs' assertions regarding relevancy are just  
8 completely unsupported.

9 I'm a little confused by Mr. Kennedy's remarks that  
10 he believes some of the assertions in our July 1st letter need  
11 expert support; I'm not sure what he's really talking about.  
12 Our main arguments are set forth in Section 2, and particularly  
13 the five uncontested, what we believe to be, material facts to  
14 the application.

15 To the extent Mr. Kennedy is talking about the  
16 argument we made regarding prejudice, the argument is simple.  
17 And that's that, you know, our API samples are expired, and  
18 they're expired for a reason. They're expired because past a  
19 certain date, like most chemical substance, they degrade, and  
20 they have an expiration date from the manufacturer which is  
21 basically the manufacturer's way of saying after this date, we  
22 can't guarantee the purity of this API. Well, purity and the  
23 presence of a certain impurity are the subject of plaintiffs'  
24 infringement allegations with respect to the impurity patents  
25 in this case.

1           So it's pretty simple. We backed up that argument  
2 with documents from plaintiffs' own production. Mr. Kennedy  
3 even admits that at least under one condition in the document  
4 we attach to our letter that the 4-Hydroxy Impurity is a  
5 degradation product.

6           So we backed up whatever factual assertions for our  
7 secondary arguments via documentary evidence from plaintiffs'  
8 production.

9           To the extent that we give them an additional  
10 declaration from our experts to support -- support anything,  
11 we'll certainly consider it. But I dispute Mr. Kennedy's  
12 argument that somehow we had a number of allegations in our  
13 letter that need expert support. Actually our principal  
14 argument is undisputed, and that is we're not going to be using  
15 unexpired API to formulate our ANDA product and API is  
16 irrelevant as far as infringement is concerned in this case  
17 because none of us are going to be importing or using our API  
18 in the United States, only our finished dosage form.

19           THE COURT: So where does that leave us, Counsel, in  
20 terms of additional submissions and what you all propose to  
21 give me for the help that I'm seeking?

22           MR. KENNEDY: Your Honor, this is Mike Kennedy for  
23 plaintiffs again.

24           Let me suggest this: Counsel are all going to see  
25 each other over the next week at a claim construction



1 deposition and then the Markman hearing.

2 THE COURT: Right.

3 MR. KENNEDY: I don't want to prolong this unduly,  
4 but I do need to consult with defendants and with my own side  
5 about what kind of schedule makes sense for an expert  
6 declaration. So would it be okay with Your Honor if in the  
7 next few days to a week, the parties submit a proposed schedule  
8 for a declaration? And in the meantime, Your Honor could hold  
9 the ruling on the motion in abeyance?

10 THE COURT: I'm fine with that, I think it makes some  
11 sense. I know you have other pressing aspects of this case,  
12 preparing for the Markman hearing. And that's on for the 12th,  
13 correct, with Judge Wolfson?

14 MR. KENNEDY: Correct.

15 THE COURT: All right. So if you can get yourselves  
16 through that exercise, and get something to me either by the  
17 end of next week or the beginning of the following week, you  
18 know, that represents some kind of a schedule for your  
19 submissions, you all can work out the staging of your  
20 submissions, I'm certainly fine with that.

21 Mr. Dansford (sic)?

22 (No audible response heard)

23 THE COURT: Did we lose you?

24 MR. KENNEDY: I'm sorry, Your Honor, it's Mr.  
25 Kennedy. I'm not sure who you were addressing.

1 THE COURT: Defense counsel.

2 MR. KENNEDY: The plaintiffs -- the plaintiffs --  
3 plaintiffs are fine -- yeah, plaintiffs are fine with your  
4 schedule.

5 THE COURT: Okay.

6 MR. ALUL: And, Your Honor --

7 MR. KENNEDY: What you're suggesting.

8 MR. ALUL: And, Your Honor, Andy Alul for the Apotex  
9 defendants.

10 We're completely fine with the Court's proposal, as  
11 well.

12 THE COURT: Okay. So informally -- I'm not holding  
13 you to this date specifically, but get through the Markman on  
14 the 12th, and by the middle of the next week, roughly the 20th,  
15 give or take a day, I'll expect to see something from you all  
16 that represents a proposal for additional submissions on the  
17 subject of plaintiffs' informal application, okay?

18 MR. ALUL: Yes, Your Honor; thank you.

19 THE COURT: All right.

20 MR. KENNEDY: That works for plaintiff, Your Honor;  
21 thank you.

22 THE COURT: Okay. So let me just address one last  
23 issue before we go. I know we said earlier that everybody was  
24 generally content with the schedule we have laid out in the  
25 scheduling order from last November, Docket Number 37. That

1 does not call for another telephone conference until October,  
2 October 3rd at 10 a.m. Is everybody okay with that timing?  
3 Understanding that I may schedule an ad hoc call or conference  
4 in the meantime once I get your additional submissions on the  
5 issue we've been discussing.

6 But on the general subject of case management, is  
7 that October 3rd date still an appropriate time as far as you  
8 all are concerned?

9 MR. KENNEDY: This is Mike Kennedy for plaintiffs.

10 We're -- we're fine with October 3rd. We would also  
11 be fine with an earlier date; whatever Your Honor prefers.

12 THE COURT: Anybody on the defense side feel  
13 differently?

14 (No audible response heard)

15 THE COURT: All right. I'm going to leave the  
16 October 3rd date in place. I'm not going to schedule anything  
17 in the interim. I may, as I said, ask for another conference,  
18 I'll post it on the docket if such a conference is necessary  
19 for me to address the issue that we've been discussing today.

20 And, of course, if anything else comes up, and you  
21 need me in the interim, you folks know where to find me. So --  
22 all right. That's all I have for today.

23 Anything else on behalf of the plaintiffs, Mr.  
24 Kennedy?

25 MR. KENNEDY: Nothing from plaintiffs, Your Honor;

1 thank you.

2 THE COURT: Okay. And anything else from any of the  
3 defendants?

4 (No audible response heard)

5 THE COURT: All right, folks, nice to talk to you.  
6 Enjoy the summer. If you're in the neighborhood next week  
7 after your Markman hearing, and you want to stop down and say  
8 hello, I'd be happy to see you.

9 MULTIPLE SPEAKERS: Thank you, Your Honor.

10 THE COURT: All right. Thank you. Bye-bye.  
11 (Whereupon, at 11:30, the hearing was adjourned.)  
12  
13

14 CERTIFICATE OF TRANSCRIBER  
15

16 I, KAREN HARTMANN, a certified Electronic Court  
17 Transcriber, certify that the foregoing is a correct transcript  
18 from the electronic sound recording of the proceedings in the  
19 above-entitled matter.  
20

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22

23 Karen Hartmann, AAERT CET\*\*D0475 Date: July 11, 2016  
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